

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 06/17/2019
FORM APPROVED
OMB NO. 0938-0391

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 503300 | (X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____ | | (X3) DATE SURVEY COMPLETED C 05/30/2019 |
| NAME OF PROVIDER OR SUPPLIER SEATTLE CHILDREN'S HOSPITAL | | | STREET ADDRESS, CITY, STATE, ZIP CODE 4800 SAND POINT WAY NE, PO BOX C-5371 SEATTLE, WA 98105 | | |
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| A 000 | <p>INITIAL COMMENTS</p> <p>MEDICARE COMPLAINT INVESTIGATION</p> <p>The Washington State Department of Health (DOH) in accordance with Medicare Conditions of Participation set forth in 42 CFR 482 for Hospitals, conducted this health and safety complaint investigation.</p> <p>Onsite dates: 05/28/19 to 05/30/19 Examination number: 2019-7126 Intake number: 90673</p> <p>The investigation was conducted by:</p> <p>Investigator #2 Investigator #3 Investigator #4</p> <p>DOH staff found the facility NOT IN COMPLIANCE with the following Conditions of Participation:</p> <p>§ 42 CFR 482.12 Governing Body § 42 CFR 482.21 Quality Assessment and Performance Improvement Program § 42 CFR 482.42 Infection Control §42 CFR 482.41 Physical Environment</p> | A 000 | | | |
| A 043 | <p>GOVERNING BODY</p> <p>CFR(s): 482.12</p> <p>There must be an effective governing body that is legally responsible for the conduct of the hospital. If a hospital does not have an organized governing body, the persons legally responsible</p> | A 043 | | | |

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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| A 043 | Continued From page 1 for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body ... This CONDITION is not met as evidenced by: . Based on observation, document review and interview, the hospital's governing body failed to provide effective oversight of the hospital. Failure to provide effective oversight for quality improvement, infection control and physical environment put patients at risk of harm from pathogenic organisms. Findings included: Due to the scope and severity of deficiencies detailed under § 42 CFR 482.21 Condition of Participation for Quality Assessment and Performance Improvement, §42 CFR 482.41 the Condition of Participation for Physical Environment, §42 CFR 482.42 Condition of Participation for Infection control, and , the Condition of Participation for Governing Body was NOT MET. Cross Reference: Tags A0263, A0700, A0747, and A0749 . | A 043 | | | |
| A 263 | QAPI CFR(s): 482.21 The hospital must develop, implement and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance | A 263 | | | |

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| A 263 | <p>Continued From page 2 improvement program.</p> <p>The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors.</p> <p>The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.</p> <p>This CONDITION is not met as evidenced by:</p> <p>Based on interview and document review, the hospital quality program failed to provide oversight of quality projects and activities related to infection control, water management and maintenance of hospital's physical environment.</p> <p>Failure to ensure that oversight of the quality program is hospital-wide and focuses on projects that prevent infections puts patients, staff and visitors at risk of harm from environmental pathogens.</p> <p>Findings included:</p> <p>1. The hospital's Quality Improvement Steering Committee failed to approve and implement the hospital's Infection Prevention Quality Assessment & Performance Improvement plan (last revised 10/05/18) that received approval from the Infection Prevention Executive Oversight Committee, as documented in meeting minutes dated 10/31/18.</p> | A 263 | | | |

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| A 263 | Continued From page 3 2. The hospital's Safety Leadership Committee failed to approve and implement the facility's draft Water Management Plan. 3. The hospital's quality program failed to ensure that facility staff completed preventive maintenance of the hospital's air handling system according to industry standards and manufacturer's recommendations. Cross Reference: A0700, A0747 Due to the scope and severity of deficiencies cited under §42 CFR 482.21, the Condition of Participation for Quality Assessment and Performance Improvement was NOT MET. | A 263 | | | |
| A 700 | PHYSICAL ENVIRONMENT CFR(s): 482.41 The hospital must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community. This CONDITION is not met as evidenced by: Based on interview and document review, facilities staff failed to perform maintenance activities on utility systems designed to control air quality as indicated in hospital policy and industry standard. Failure to perform timely preventive maintenance | A 700 | | | |

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| A 700 | Continued From page 4 for utility systems puts patients at risk of harm from airborne contaminants. Findings included: The facilities staff failed to replace pre-filters on the hospital air-handling units every three months as stated by the Building Operations Manager (Staff #201). The facilities staff failed to calibrate or validate the equipment used to test filter efficacy and airflow rates. The hospital staff failed to develop a risk classification to prioritize maintenance of the system's utility equipment. Cross Reference: A0724 Due to the scope and severity of deficiencies cited under §42 CFR 482.41, the Condition of Participation for Physical Environment was NOT MET. | A 700 | | | |
| A 724 | FACILITIES, SUPPLIES, EQUIPMENT MAINTENANCE CFR(s): 482.41(d)(2) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality. This STANDARD is not met as evidenced by: Based on record review and interview, the hospital facilities staff failed to complete | A 724 | | | |

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| A 724 | <p>Continued From page 5</p> <p>preventive maintenance at required intervals for air handlers in the operating room, failed to inspect and calibrate filter performance, air pressure, and airflow monitoring equipment to ensure accuracy, and failed to maintain written criteria to assign priority levels and maintenance schedules for utilities equipment.</p> <p>Failure to conduct preventive maintenance activities at required intervals, validate the accuracy of testing equipment, and define criteria for assignment of priority levels and maintenance schedules risks inadequate function of utility systems that could place patients, staff, and visitors at risk of exposure to poor air quality, infection, or injury.</p> <p>Findings included:</p> <p>1. On 05/29/19 at 11:00 AM, Investigator #2 interviewed the Building Operations Manager (Staff #201) regarding the preventive maintenance process for the air handlers serving the operating rooms. The interview showed the following:</p> <p>a. Staff #201 stated that the air handlers and exhaust fans are on a quarterly maintenance cycle and the technician has the entire three-month period to complete the required maintenance. Staff #201 reviewed the preventive maintenance records with the investigator and confirmed that the maintenance activities for the prior year did not fit the desired quarterly intervals due to the tracking system allowing technicians the entire interval period to complete maintenance activities.</p> <p>b. Staff #201 stated that technicians are to</p> | A 724 | | | |

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| A 724 | <p>Continued From page 6</p> <p>change the pre-filters every three months or more often if their condition warrants.</p> <p>2. Record review of the document titled, "Utility Systems Management Plan," no policy number, revised 03/06/19, showed that the Building and Engineering department is to use written criteria to identify utility risks, which the department uses along with manufacturer's recommendations and hospital experience to determine maintenance strategies. The review also showed that the Building and Engineering department is required to inspect filter performance monitoring equipment, air pressure sensing equipment, and airflow rate sensors according to departmental-developed schedules.</p> <p>3. Record review of the 2018 and 2019 preventive maintenance records for the air handlers and associated exhaust fans serving the operating rooms showed that the hospital did not conduct preventative maintenance on quarterly intervals. The review also showed that technicians did not change pre-filters every three months or at subsequent maintenance activities as indicated on the maintenance records. The review showed the following:</p> <p>a. The preventive maintenance task sheet for the air handler units stated to inspect the air filters and replace based on inspection results.</p> <p>b. Air Handler 1 (AHU-1) had quarterly preventive maintenance completed on 07/22/18 for the quarter from 05/04/18 to 08/02/18. The technician (Staff #204) did not change the pre-filters and indicated them as having "OK" status.</p> <p>c. AHU-1 and Air Handler 1R (AHU-1R) had</p> | A 724 | | | |

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| A 724 | <p>Continued From page 7</p> <p>quarterly preventive maintenance completed on 10/03/18 for the quarter from 08/03/18 to 11/01/18. The technician (Staff #204) did not change the pre-filters and indicated them as in need of replacement at the next service.</p> <p>d. AHU-1 and AHU-1R had quarterly preventive maintenance on 11/05/18 for the quarter from 11/02/18 to 01/30/19, a gap of one month from the previous maintenance. The technician (Staff #204) indicated that the pre-filters needed replacement at the next service.</p> <p>e. AHU-1 and AHU-1R had quarterly preventive maintenance on 04/03/19 and 04/29/19, respectively, for the quarter from 02/01/19 to 05/02/19, a gap of five months for AHU-1 and six months for AHU-1R from the previous maintenance. The technician (Staff #204) indicated that he replaced the pre-filters during these services.</p> <p>f. Review of the past year's maintenance records for AHU-1, showed that there was no documentation that the hospital replaced the pre-filters from 05/04/18 to 04/03/19, a period of almost one year. Review showed that there was no documentation the hospital changed filters for AHU-1R from 08/03/18 to 04/29/19.</p> <p>4. Record review of the 2018 and 2019 preventive maintenance records for the exhaust fans serving the operating rooms showed the following:</p> <p>a. Exhaust Fan 1 (EF-1) and Exhaust Fan 1R (EF-1R) had quarterly preventive maintenance completed on 08/28/18 and 09/27/18, respectively, for the quarter from 07/02/18 to 09/30/18.</p> | A 724 | | | |

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| A 724 | Continued From page 8 b. EF-1 and EF-1R had quarterly preventive maintenance completed on 11/08/18 for the quarter from 10/01/18 to 12/29/18. c. EF-1 and EF-1R had quarterly preventive maintenance completed on 04/03/19 and 03/29/19, respectively, for the quarter from 01/07/19 to 04/07/19, a period of approximately five months for the last maintenance activity. 5. On 05/30/19 at 2:37 PM, Investigator #2 interviewed the Building Operations Manager (Staff #201) a second time regarding air handler maintenance intervals, testing of air and filter monitoring equipment, and the priority classification assigned to utilities equipment. The interview showed the following: a. Staff #201 again confirmed that technicians are required to change the pre-filters every three months as part of preventive maintenance activities. b. Staff #201 stated that he was unaware what risk assessment or classification the hospital used to identify maintenance strategies for utility equipment. Staff #201 was unable to provide any written documentation that showed completion of a risk assessment or establishment of risk criteria. c. Staff #201 stated that the department was not currently inspecting, validating, or calibrating equipment used to monitor filter performance, air pressure, or airflow rates within the facility and had not developed schedules as specified in the utilities management plan. | A 724 | | | |

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| A 747 | <p>INFECTION CONTROL CFR(s): 482.42</p> <p>The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.</p> <p>This CONDITION is not met as evidenced by:</p> <p>Based on observation, interview, and document review, the hospital failed to develop and implement an effective infection prevention and control program.</p> <p>Failure to develop and implement an effective infection prevention and control program puts patients, staff and visitors at risk of illness from communicable diseases.</p> <p>Findings included:</p> <p>The hospital's infection prevention staff failed to follow hospital policy for approving the annual Infection Prevention Quality Plan</p> <p>The hospital's infection prevention staff failed to approve and implement the Water Management & Waterborne Pathogen Prevention Plan</p> <p>The hospital failed to ensure that decontamination products used in an endoscope reprocessor were not expired.</p> <p>Cross Reference: Tag A0749</p> <p>Due to the scope and severity of deficiencies cited under §42 CFR 482.42, the Condition of</p> | A 747 | | | |

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| A 747 | Continued From page 10 Participation for Infection Control was NOT MET. | A 747 | | | |
| A 749 | INFECTION CONTROL PROGRAM CFR(s): 482.42(a)(1) The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel. This STANDARD is not met as evidenced by: . Based on observation, interview, and document review, the hospital infection prevention staff failed to follow hospital policy for approval of their annual Infection Prevention Quality Program Charter (1), failed to approve and implement the hospital's draft water management plan (2), and failed to ensure that decontamination products used in an endoscope reprocessor were not expired (3). Failure to implement and manage elements of the hospital's infection control program puts patients, staff, and visitors at risk of illness from communicable diseases. Findings included: Item #1- Approval of the Annual Infection Prevention Plan 1. Document review of the hospital's "Infection Prevention Quality Assessment and Performance Improvement Plan FY 2019," (revised 10/05/18) | A 749 | | | |

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| A 749 | <p>Continued From page 11</p> <p>showed that the Infection Prevention Quality Program is reviewed and revised every year or as necessary. Approval is required by two committees (Infection Prevention Executive Oversight Committee and the Quality Improvement Steering Committee) before the plan is adopted. The corresponding committee meeting minutes will record their approval.</p> <p>Document review of the hospital's Infection Prevention Executive Oversight Committee (IPEOC) meeting minutes dated 10/31/18 showed that the IPEOC team approved the FY 19 Infection Prevention Quality Assessment & Performance Improvement plan (last revised 10/05/18). Under the section titled "Action Items for this Committee," the annotated minutes read, "send FY QAPI, Charter, and Risk Assessment to QISC for their approval and records".</p> <p>2. On 05/30/19 at 12:58 PM, Investigator #3 interviewed the Director of Quality Services (Staff #301) about approval of the Infection Prevention plan. Staff #301 stated the infection prevention plan is scheduled for presentation and approval at the upcoming June 2019 Quality Improvement Steering Committee (QISC) meeting.</p> <p>Item #2- Water Management Plan</p> <p>1. Record review of the document titled, "Water Management & Waterborne Pathogen Prevention Plan," updated 04/12/19, showed that the facility would conduct water system monitoring of free chlorine levels, water temperature, and water pH at monthly intervals for the first year of the plan and at other scheduled intervals thereafter as determined by the initial testing. The review also showed that the facility would conduct quarterly</p> | A 749 | | | |

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| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | ID PREFIX TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) | (X5) COMPLETION DATE | |
| A 749 | <p>Continued From page 12</p> <p>water testing for Legionella for the first year of the program and at other scheduled intervals as determined by the initial year of testing.</p> <p>Record review also showed that the water management plan was still a draft document.</p> <p>2. On 05/29/19 at 11:00 AM, Investigator #2 interviewed the Building Operations Manager (Staff #201) regarding the hospital water management plan. Staff #201 stated that the Facilities department coordinates the routine maintenance of cooling towers, ice machines, and utility systems as defined in the plan but is not currently performing Legionella testing.</p> <p>3. On 05/29/19 at 12:00 PM, Investigator #2 interviewed the Director of Accreditation and Regulatory Compliance (Staff #202) regarding the water management plan. Staff #202 stated that the water management plan was still a draft document and that the hospital was not performing water system testing and Legionella testing as outlined in the plan.</p> <p>4. On 05/29/19 from 3:00 to 4:00 PM, Investigators #2, #3, and #4 conducted an Infection Control Program review with various hospital staff members. During the review, Surveyor #2 asked the Director of Infection Prevention (Staff #203) if the hospital had finalized the water management plan and implemented all of its components. Staff #203 confirmed that the plan was still a draft document and the Safety Leadership Committee had not formally approved the plan. Staff #203 also confirmed that the hospital was not currently conducting water system monitoring or Legionella testing and analyzing the results as required in</p> | A 749 | | | |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

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| A 749 | <p>Continued From page 13 the plan.</p> <p>Item #3- Endoscope Reprocessing</p> <p>1. On 05/29/19 at 10:00 AM, Investigator #4 toured the sterile processing department at the Bellevue Clinic and Surgery Center. The surveyor toured the decontamination room, which included a Steris Endoscope Reprocessing unit used for reprocessing of endoscopes used for ear, nose, and throat procedures. The observation showed the bottle of "CIP 200," an acid cleaner used as part of the decontamination cycle had an expiration date of February 2019.</p> <p>2. At the time of the observation, Investigator #4 asked a sterile processing technician (Staff #401) about the expired product. The staff member stated she was unaware that the product had expired and that the service vendor usually checks the unit's accessories during service calls. The investigator and the staff member also reviewed the list of the machine's automated alerts. There was no system alert for the cleaning products.</p> <p>.</p> | A 749 | | | |